

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Age Requirement
Date: Wednesday, October 14, 2020 11:33:00 AM

Good morning -

Please see the FDA link that outlines Additional Protections for Children - <https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/additional-protections-children#:~:text=Children%20are%20defined%20as%20persons,clinical%20investigation%20will%20be%20conducted>

Specifically please see # 5. However the entire document is worth reading.

The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines pediatric patients as persons aged 21 or younger at the time of their diagnosis or treatment. Pediatric subpopulations are further categorized as follows: Neonates - (from birth through the first 28 days of life). Infants - (29 days to less than 2 years)

Please see FDA's Office of Pediatric Therapeutics - <https://www.fda.gov/about-fda/office-clinical-policy-and-programs/office-pediatric-therapeutics>

Informed consent might be needed for your study. Please see the FDA's guidance on informed consent - <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guide-informed-consent>

And *draft* guidance for 2014 - <https://www.fda.gov/media/88915/download> Please see section F. Children as subject.

Kind regards,

Doreen M. Kezer, MSN

Senior Health Policy Analyst

Office of Clinical Policy and Programs

Office of Good Clinical Practice (OGCP)

U.S. Food and Drug Administration

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-----Original Message-----

From: [REDACTED]
Sent: Tuesday, October 13, 2020 2:51 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Age Requirement

Hello,

We are conducting a household travel survey that offers the option for household members to participate via mobile app. I am curious if there are any guidelines around cutoff ages for this type of thing? IE does a participant need to be at least 18? Since the whole household participates I assume if the parents are okay with a 14 year old participating on their phone it should be okay? Thanks for your help.

Sent from my iPhone